

# EXHIBIT 3

*Dental  
concepts*

## HOGAN & HARTSON

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October 20, 2006

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Partner  
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**BY ELECTRONIC MAIL AND HAND DELIVERY**

Mr. Timothy A. Ulatowski  
Director, Office of Compliance (HFZ-300)  
Center for Devices and Radiological Health  
Food and Drug Administration  
2094 Gaither Road  
Rockville, MD 20877

**Re: SleepRight® Adjustable Night Guard**

Dear Mr. Ulatowski:

It has come to our attention that Splintek® is currently promoting its line of SleepRight® Adjustable Night Guard ("SleepRight") devices for over-the-counter ("OTC") use to "protect teeth from clenching & grinding." Our review of the Food and Drug Administration's ("FDA") premarket notification ("510(k)") database shows that Splintek apparently has not obtained FDA premarket clearance or approval to commercially distribute this device for OTC use.

### **I. BACKGROUND**

Dental mouthguards are unclassified devices. Persons intending to market a dental mouthguard must submit and obtain FDA clearance of a 510(k) notification before marketing the device. To date, only one manufacturer (*i.e.*, Dental Concepts L.L.C.) has obtained 510(k) clearance for marketing a mouthguard for OTC use in protecting teeth against bruxism or nighttime teeth grinding (K053580).

All other dental mouthguards that received FDA premarket clearance have been restricted to prescription use. These devices are presently cleared for the following indications for use:

for protection against tooth grinding, bruxism, and jaw clenching  
that may be associated with temporomandibular disorders  
syndrome or orofacial pain; also to provide short term pain relief

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from muscle spasm associated with occlusal interference or with increased muscular activity.

FDA's 510(k) database indicates that the agency cleared Splintek's EZ Splint and EZ Splint PM oral occlusal appliance or splint devices on October 17, 2003 (K022809). The FDA cleared the device for use to protect against teeth grinding, bruxism, and jaw clenching; for short-term pain relief from muscle spasm due to occlusal interference; and for the prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the posterior mandibular and maxillary teeth. FDA cleared the device only for prescription use.

- The attached, as well as the web site claims referenced below, are promotional material (**Attachment 1**) distributed by Splintek for the SleepRight Adjustable Night Guard, which they promote for OTC use.

Splintek's web site ([www.sleepright.com](http://www.sleepright.com)) also contains information regarding its line of SleepRight devices (**Attachment 2**). That information describes the following three SleepRight devices: (1) Sleep Right Adjustable Night Guard Advance; (2) Sleep Right Adjustable Night Guard Select; and (3) SleepRight Adjustable Night Guard Select Low-Profile.

The Advance night guard is promoted as "New & improved to be more durable, comfortable, and stable." The Select night guard is promoted as the "Original design that fits most individuals and recommended for sleep." The Select Low-Profile night guard is "Recommended for sensitive gums and/or a small mouth."

The information on Splintek's web site also contains the following statements:

"Can also be worn for performance enhancement during non-contact sporting activities where the natural tendency to clench and grind teeth may occur, such as: golf, weightlifting, tennis, cycling, bowling, archery, skeet shooting, etc."

"Clenching and grinding teeth has been classified as a neuromuscular disorder. Overactive muscles can cause chipping, fractures, excessive wear, and loosening of the teeth. So studies report that chronic jaw clenching and teeth grinding may be related to head and neck muscle tension and pain in the jaw joints. xxx"

"Caution: For all TMJ concerns, please consult your health care provider who may prescribe a SleepRight Rx. Do not use for more than 12 hours in a 24 hour period. Recommended for day time or night time use, not both. Not for children under 12 years of age. If you experience jaw pain, clicking, jaw noises, tooth movement, or other symptoms, see your health care provider. Discontinue use and replace if breakage occurs."

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Splintek's web site lists the company's address as 3325 Wyoming St., Kansas City, MO 64111. The web site also show the following telephone contact information: Toll-Free (800) 792-0865; Local (816) 531-1900; and Fax (816) 531-1968.

### III. REGULATORY REQUIREMENTS

Recommending or suggesting OTC use of a device that FDA has cleared only for prescription use creates a new intended use, which requires the person marketing the device to obtain agency clearance of a new 510(k) notification. 21 C.F.R. § 807.81(a)(3). Until FDA clears the device for marketing for OTC use, the agency deems the device to be adulterated under Section 501(f) of the FDC Act because it is a class III device for which FDA has not approved a premarket approval application or an application for an investigational device exemption. The manufacturer also must ensure that adequate directions for use of the device by the layperson are provided in the device's labeling. Absent such directions for use, the device is misbranded under Section 502(f)(1) of the FDC Act.

### IV. ANALYSIS

As discussed above, promotional information for the SleepRight Adjustable Night Guards that is being distributed by Splintek or appears on Splintek's web site claims that the device is available for OTC use to protect teeth and dental work from clenching and grinding and is "designed specifically to protect teeth from bruxism, commonly referred to as clenching and grinding the teeth." The information on the Splintek website also states: "Studies has (sic) reported that chronic jaw clenching and grinding has been associated with head, neck, shoulder, and back tension." It appears that Splintek is promoting and marketing its line of SleepRight Adjustable Night Guards for OTC use without first obtaining FDA clearance of a new 510(k) in accordance with 21 C.F.R. § 807.81(a)(3).

The Dental Products Panel ("Panel"), at its meeting on October 12, 2005, discussed the appropriate design of a dental mouthguard marketed for OTC use. In response to the Panel Chairperson's question (Dr. Suzuki) as to whether FDA had a question on appropriate design, FDA's representative (Dr. Mulry) responded: "I think we were kind of looking to have some input on full versus partial coverage and then soft versus hard, whether there would be any differentiation in OTC for one versus the other." Panel transcript p. 172. The Panel concluded that the OTC design should be full coverage and it does not matter whether the device is hard or soft as long as there are adequate labeling instructions. Panel transcript p. 173. It appears that "full coverage" means that the mouthguard covers all of the teeth, including the molars and that "partial coverage" means that the mouthguard covers only some of the teeth in the dental arch.

The Dental Concepts "Nightguard" is a full-coverage device. The Splintek SleepRight is a partial-coverage device because it allows the patient to bite down only on the rear molars, not on all of the teeth in the dental arch.

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The Dental Products Panel concluded that only full-coverage mouthguards should be available for OTC use. Therefore, the Panel would not regard the Splintek SleepRight, which is a partial-coverage device, to be suitable for OTC use.

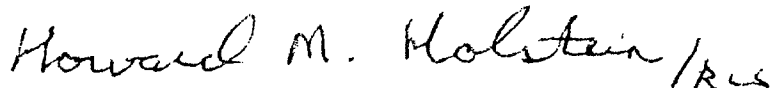
**V. CONCLUSION**

In sum, Splintek is promoting and marketing its line of SleepRight Adjustable Night Guards for OTC used to protect teeth from clenching and grinding without having first obtained FDA clearance or approval for these OTC claims or for a partial-coverage design. Therefore, when promoted for these non-FDA cleared or approved claims, the SleepRight devices are adulterated and misbranded. We request that the Office of Compliance take appropriate enforcement actions to prevent Splintek from continuing to distribute the adulterated and misbranded line of SleepRight Adjustable Night Guards as OTC devices to protect teeth from clenching and grinding.

\* \* \* \* \*

Please call me if you have any questions regarding this letter or if we can be of further assistance in FDA's investigation of this matter.

Sincerely,

A handwritten signature in cursive script that reads "Howard M. Holstein / RLS".

Howard M. Holstein

Attachments

cc: Robert L. Spencer, Esq.

**ATTACHMENT 1**

Teeth grinding? You need to know what this is.



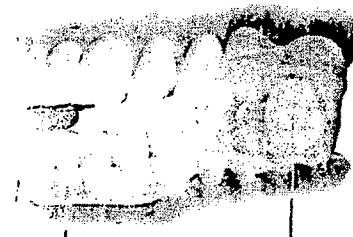
## SleepRight® Adjustable Night Guard



- Fits comfortably to protect teeth from clenching & grinding
- No boiling, not bulky, fits all sizes
- Designed by a dental specialist
- Most durable guard available, backed by a 90-day warranty

\$69.95 (plus shipping & handling)  
30-day money back guarantee

**Splintek®** Designing Health & Comfort



Shapes at Body  
Temperature

Adjustable Technology  
4 Bitepad Positions

Contact us to order, receive FREE information, or find a dealer near you.

**1.888.792.0865 • [sleepright.com](http://sleepright.com)**

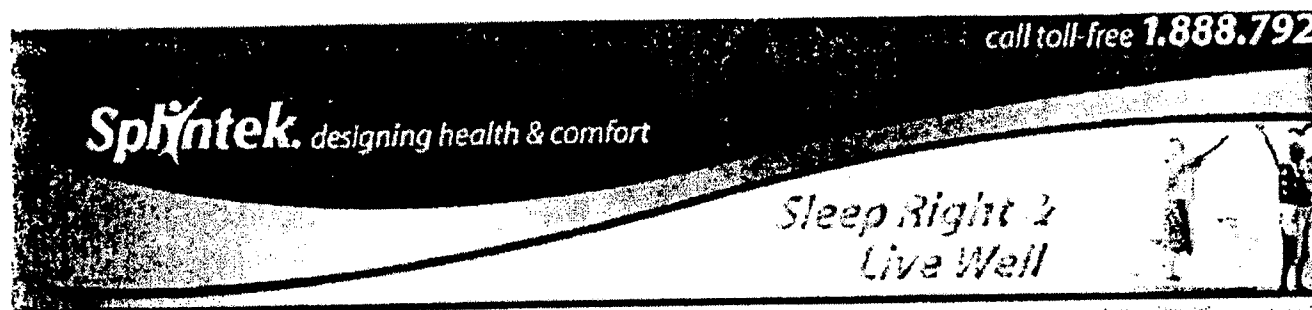
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**ATTACHMENT 2**



SleepRight Night Guard Protects Teeth From Teeth Grinding and Clenching

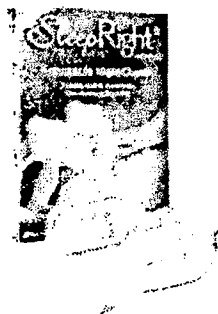
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New! SleepRight  
Adjustable Night  
Guard  
**Advance**



New & improved to be  
more durable,  
comfortable, and stable.  
> more information

Select Flavor

Buy Now

Only available here!

\$99.95 (\$89.95 for 2 or  
more)

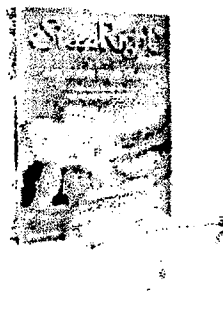
Available in a natural  
mint flavor

30-day -  
money back guarantee

30-day -  
replacement warranty

Includes one night  
guard, one carrying  
case, and fitting  
instructions.

SleepRight Adjustable  
Night Guard  
**Select**



Original design that fits  
most individuals and  
recommended for sleep.

&gt; more information

Select Flavor

Buy Now

\$69.95 (\$59.95 for 2 or  
more)

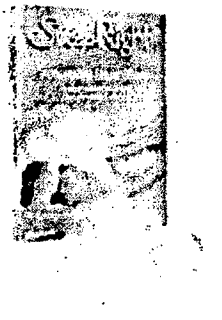
Available in natural mint  
flavor or cinnamon flavor

30-day -  
money back guarantee

30-day -  
replacement warranty

Includes one night  
guard, one carrying  
case, and fitting  
instructions.

SleepRight Adjustable  
Night Guard  
**Select Low-Profile**



Recommended for  
sensitive gums and/or a  
small mouth.

&gt; more information

Select Flavor

Buy Now

\$69.95 (\$59.95 for 2 or  
more)

Available in natural mint  
flavor or cinnamon flavor

30-day -  
money back guarantee

30-day -  
replacement warranty

Includes one night  
guard, one carrying  
case, and fitting  
instructions.

SleepRight  
**Side Sleeping  
Pillow**



Uniquely designed  
memory foam pillow for  
side sleepers.

&gt; more information

Select Size

Buy Now

\$69.95 - 16" Length  
\$99.95 - 24" Length

5-Year Warranty

All sales final on pillow

Includes one memory  
foam pillow and one  
washable, hypo-  
allergenic cotton velvet  
cover.

**ErgoPic**

Ergonomically  
dental pics.  
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Please call to c  
1.888.792.0861

\$6.95

Includes 50 ret  
dental pics and  
carrying case.

## SleepRight Night Guard Protects Teeth From Teeth Grinding and Clenching

Page 2 of 2

**SleepRight System!** Purchase a 16" pillow for \$30, or a 24" pillow for \$50, or a 24" x 5" pillow for \$60 when you purchase it with SleepRight Adjustable Night Guard! Must place your order over the phone to receive this discount. 1.888.792.0865

Orders placed after 12pm CST will be shipped out the next business day.

Orders placed after 12pm CST on a Friday, Saturday, or Sunday will be shipped out the following Monday, despite the chosen shipping method.

The SleepRight Adjustable Night Guard is not recommended without a prescription for people with disorders of the temporomandibular joint (TMJ or TMD). TMJ problems can only be diagnosed by a dentist or health professional. SleepRight Adjustable Night Guard is available by prescription for different intended uses that can only be diagnosed by a health professional.

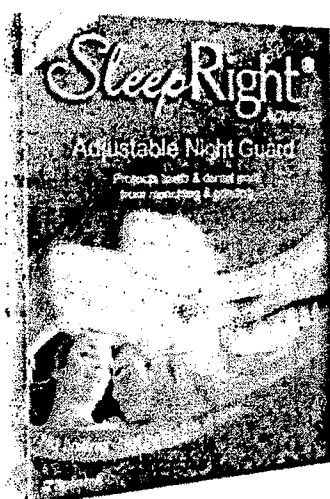
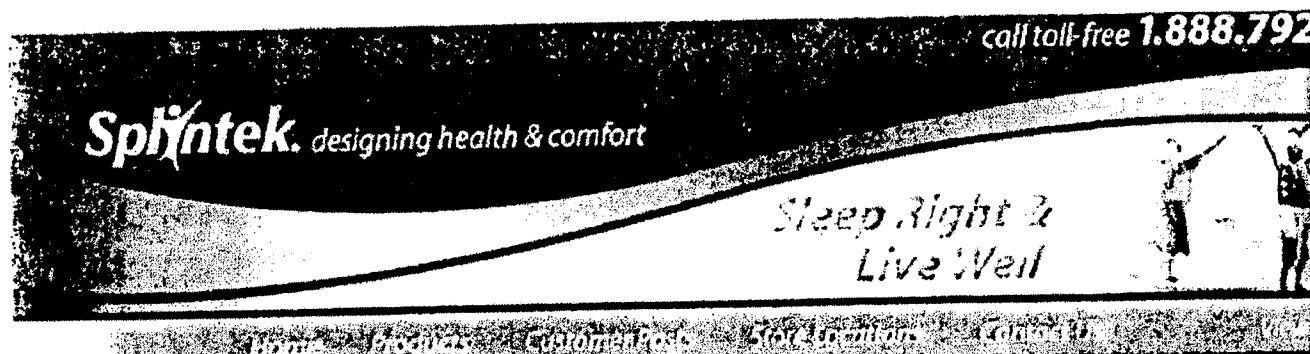
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SleepRight Night Guard Protects Teeth From Teeth Grinding and Clenching


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SleepRight

SleepRight Select  
SleepRight Select Low-Profile

Frequently Asked Questions  
Philosophy  
Care & Fitting Instructions  
Satisfied Customers

 SleepRight Advance is our new & improved design that is more durable, stable, and comfortable!

Select Flavor

Buy Now

Only available here!

\$99.95 each (89.95 each for 2 or more)

Available in a natural mint flavor.

Includes one night guard, one carrying case, and fitting instructions.

**30-Day Money Back Guarantee**  
If you are dissatisfied with the SleepRight Night Guard for any reason, simply return it to the place of purchase within 30-days from original purchase date for a refund.

**90-Day Replacement Warranty**  
SleepRight is the most durable night guard on the market. If you clench or grind though the SleepRight Night Guard within 90-days from original purchase date,

Splintek has improved the design of the **bitepads**, the **frontal band**, and the **stability** make the SleepRight Advance more durable, comfortable, and stable than the SleepRight Select. The Advance bitepads are more durable because they are engineered using a dense, higher quality material. The wider frontal band is anatomically designed with a bridge to prevent the strap from sliding and feature more bendable hinges to reduce pressure points. The stability wing is more flexible allowing the wings to move with your mouth for increased comfort.

- Protects teeth and dental work from clenching and grinding
- Designed by a dentist
- Adjustable technology designed to fit all sizes
- No boiling required
- Easy to fit in seconds
- Comfortable and not bulky

The SleepRight Adjustable Night Guard was designed by a specialist in dentistry and has been used by thousands of doctors worldwide. The SleepRight's state-of-the-art technology designed specifically to protect teeth from bruxism, commonly referred to as clenching grinding the teeth. Studies have reported that chronic jaw clenching and grinding has been associated with head, neck, shoulder, and back tension.

Can also be worn for performance enhancement during non-contact sporting activities where the natural tendency to clench and grind the teeth may occur, such as: golf, weightlifting, tennis, cycling, bowling, archery, skeet shooting, etc.

**How does the SleepRight Night Guard work?**

simply send the used night guard to Splintek, 3325 Wyoming St., Kansas City, MO 64111. You must include proof of purchase, your name, and return address. Please allow up to 2 weeks to receive your replacement.

**Indications:** SleepRight Adjustable Night Guard protects teeth and dental work from clenching and grinding.

**Caution:** For all TMJ concerns, please consult your health care provider who may prescribe a SleepRight Rx. Do not use for more than 12 hours in a 24 hour period. Recommended for day time or night time use, not both. Not for children under 12 years of age. If you experience jaw pain, clicking, jaw noises, tooth movement, or other symptoms, see your health care provider. Discontinue use and replace if breakage occurs.

Clenching and grinding teeth has been classified as a neuromuscular disorder. Overexerted muscles can cause chipping, fractures, excessive wear and loosening of the teeth. So studies report that chronic jaw clenching and teeth grinding may be related to head and neck muscle tension and pain in the jaw joints. The SleepRight's articulating bitepads, made of resilient hybrid material, slip comfortably between your teeth and are designed to re-establish your natural freeway space. While the SleepRight protects teeth from clenching and grinding, we emphasize and strongly encourage our customers to concentrate on, "lips together, teeth apart" lips together, teeth apart" to initiate the muscle relaxation learning process. When directed by the brain, muscles at ease will allow the teeth to rest on the bitepads. Do not force them down, although the natural urge to do so will test your mental approach to learning "lips together, teeth apart".

### How do I fit the SleepRight Night Guard?

Detailed pictures are included with easy to follow care and fitting instructions. With SleepRight's patented adjustable technology, you have four bitepad positions, making it easy to customize the size to fit most people. The thermal sensitive strap, which is positioned between your lower lip and teeth, will adapt to your gums when heated under warm water. Do not boil the SleepRight Night Guard.

### How does the SleepRight Night Guard stay in place?

The SleepRight Night Guard utilizes natural tissue retention between your lips, cheek, and tongue to be held in place. There are no clasps that attach to the teeth and you do not need to hold the appliance in place. While the bitepads are made of a tough and resilient material, the heat sensitive memory strap is smooth, soft, and flexible. This enhances adaptation to each individual's anatomy.

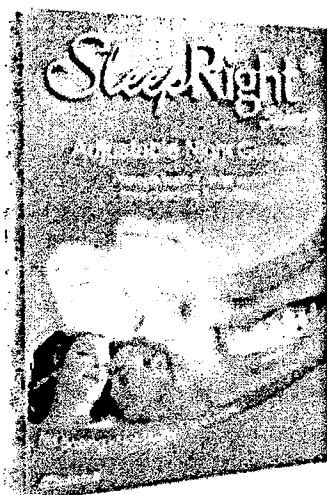
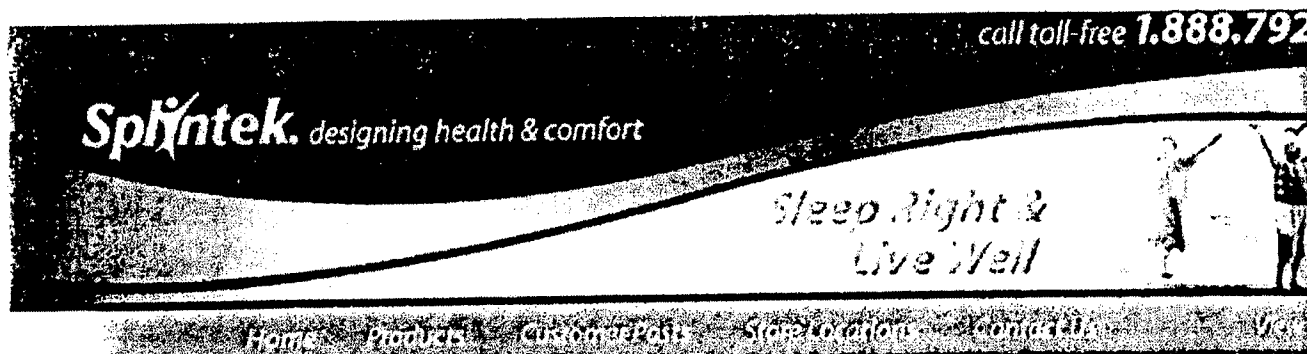
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SleepRight Night Guard Protects Teeth From Teeth Grinding and Clenching

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# SleepRight<sup>®</sup>

## Select

SleepRight Advance  
SleepRight Select Low-Profile

Frequently Asked Questions  
Philosophy  
Care & Fitting Instructions  
Satisfied Customers



SleepRight Select is the original design that fits n individuals and recommended for sleep.

Select Flavor

Buy Now

\$69.95 each (59.95 each for 2 or more)

Available in natural mint flavor or cinnamon flavor.

includes one night guard, one carrying case, and fitting instructions.

**30-Day Money Back Guarantee**  
If you are dissatisfied with the SleepRight Night Guard for any reason, simply return it to the place of purchase within 30-days from original purchase date for a refund.

**90-Day Replacement Warranty**  
SleepRight is the most durable night guard on the market. If you clench or grind though the SleepRight Night Guard within 90-days from original purchase date, simply send the used night guard to

- Protects teeth and dental work from clenching and grinding
- Designed by a dentist
- Adjustable technology designed to fit all sizes
- No boiling required
- Easy to fit in seconds
- Comfortable and not bulky

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Can also be worn for performance enhancement during non-contact sporting activities the natural tendency to clench and grind the teeth may occur, such as: golf, weightlifting, tennis, cycling, bowling, archery, skeet shooting, etc.

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## SleepRight Night Guard Protects Teeth From Teeth Grinding and Clenching

Page 2 of 2

Splintek, 3325 Wyoming St., Kansas City, MO 64111. You must include proof of purchase, your name, and return address. Please allow up to 2 weeks to receive your replacement.

**Indications:** SleepRight Adjustable Night Guard protects teeth and dental work from clenching and grinding.

**Caution:** For all TMJ concerns, please consult your health care provider who may prescribe a SleepRight Rx. Do not use for more than 12 hours in a 24 hour period. Recommended for day time or night time use, not both. Not for children under 12 years of age. If you experience jaw pain, clicking, jaw noises, tooth movement, or other symptoms, see your health care provider. Discontinue use and replace if breakage occurs.

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### How does the SleepRight Night Guard stay in place?

The SleepRight Night Guard utilizes natural tissue retention between your lips, cheek, and tongue to be held in place. There are no clasps that attach to the teeth and you do not need to hold the appliance in place. While the bitepads are made of a tough and resilient material, the heat sensitive memory strap is smooth, soft, and flexible. This enhances adaptation to each individual's anatomy.

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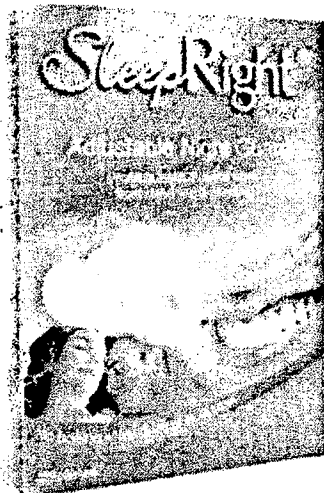
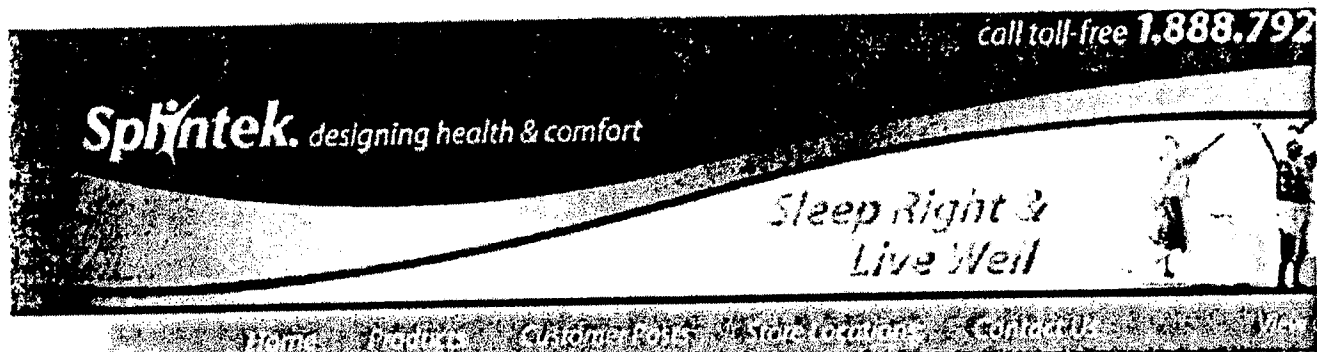

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SleepRight Night Guard Protects Teeth From Teeth Grinding and Clenching

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*Low-Profile**SleepRight*  
*Select*SleepRight **Advance**  
SleepRight **Select**Frequently Asked Questions  
Philosophy  
Care & Fitting Instructions  
Satisfied Customers
 SleepRight Select Low-Profile is recommended for sensitive gums and/or a small mouth.

Select Flavor

**Buy Now**

\$69.95 each (59.95 each for 2 or more)

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adaptation to each individual's anatomy.

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SleepRight Memory Foam Pillow Provides Orthopedic Support For Side Sleeping

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call toll-free 1.888.792

**Splintek.** designing health & comfort*Sleep Right &  
Live Well*

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## SleepRight™ Side Sleeping Pillow

Helpful Hints  
Satisfied Customers  
Pillow Sizing Tool

Sleep studies indicate that side sleeping habits are 95% more prevalent when compared to sleeping on the back. Orthopedically correct side sleeping posture is now made possible by the latest in sleep technology with the SleepRight Side Sleeping Pillow. With the SleepRight state-of-the-art design, you can expect restful sleep with maximum support and superior comfort for the head, neck, and shoulders.

### What is the SleepRight Pillow made of?

The SleepRight Side Sleeping Pillow is made from premium Visco-elastic memory foam, originally developed by NASA. This pressure relieving memory foam is sensitive to body temperature and weight, easily conforming to your own personal anatomy. We guarantee our pillows to be made of the highest quality memory foam available with a 5-year warranty. Includes a machine washable, hypo-allergenic, cotton velour cover. However, if desired, your favorite standard pillowcase provides a nice feel without the velour cover.

### How does the SleepRight Pillow work?

The Visco-elastic memory foam conforms to your facial contours by taking an impression of your head and neck anatomy. This greatly minimizes the unwanted side effects of pressure points, which is a benefit unavailable in regular pillows. As your head settles into the full facial cradle, the memory foam will softly conform to your personal anatomy. The memory foam will automatically adjust to your body temperature and head weight as your head and neck stabilize in its resting place. When equalization between head weight and the elasticity of the memory foam is achieved, your head and neck posture will be ideally aligned with your spinal column.

### The Design

The SleepRight Side Sleeping Pillow has three important design features, which distinguish it from all other memory foam pillows.

The full facial cradle gently cradles the face while reduces pressure points on the jaw and ear. This means increased blood flow to the facial dermal cells while sleeping, reducing the tendency for facial tissues to crease or sag.

The 12° shoulder cradle accommodates the acute angle between



Select Size

**Buy Now**

16" x 12" x 3" - \$69.95  
16" x 12" x 4" - \$69.95  
24" x 12" x 3" - \$99.95  
24" x 12" x 4" - \$99.95  
24" x 12" x 5" - \$109.95

16" Length - Ideal for travel  
24" Length - Standard pillow that fits most pillow

3" Petite Adult - For 5'4" and shorter  
4" Standard Adult - For 5'5" and taller  
5" Large Adult - For 5'10" and taller (broad shot large frames)

Includes one memory foam pillow and one machine washable, hypoallergenic, cotton velour cover.

**SleepRight System!** Purchase a 16" pillow for 24" pillow for \$50 when you purchase it with a SleepRight Adjustable Night Guard! Must place

## SleepRight Memory Foam Pillow Provides Orthopedic Support For Side Sleeping

Page 2 of 2

your head, neck, and shoulder while sleeping on your side. You will experience significant improvement in your spinal alignment between the neck and back. The anatomical shoulder cradle will reduce the body weight impact on the shoulders, increasing blood flow to the arms.

The left and right airway system maximizes airflow to help you experience improved breathing. Some users have reported a reduction in snoring.

order over the phone to receive this discount.  
1.888.792.0865

All sales are final on bedding products.

### 5-Year Warranty

You may exchange the SleepRight Side Sleepir for a replacement within 5 years from the original purchase date. Simply send the used pillow to 53325 Wyoming St., Kansas City, MO 64111. You include proof of purchase, your name, and return address. Please allow up to 2 weeks to receive replacement.

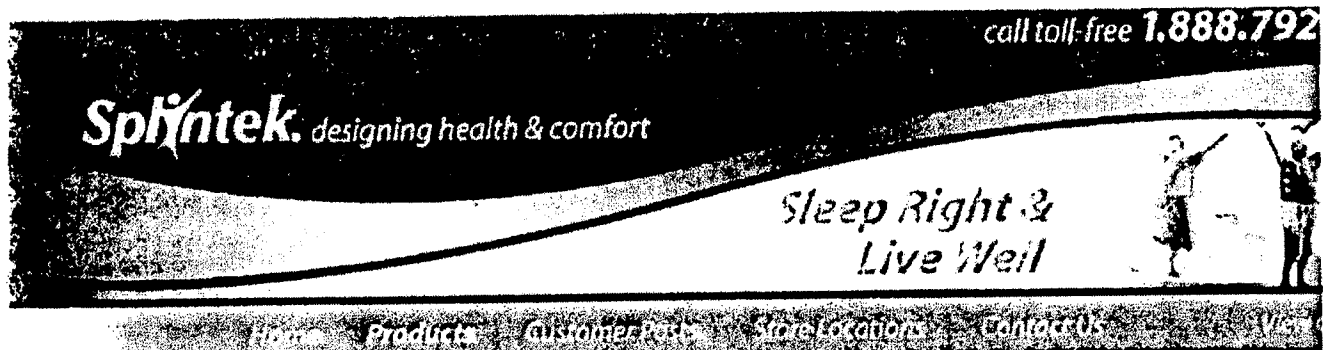
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## ERGOPIC

The ErgoPic is designed with an easy to hold ergonomic finger tab and two different tips. One tip features a patented cleaning texture for interproximal cleaning between teeth. The other is designed to clean plaque around gum lines while stimulating healthy gingival tissues. Each pic is made of durable polypropylene for extended use without splintering or breaking.

Please call to order: 1.888.792.0865

\$6.95

includes 50 dental pics and one carrying case.

Stimulates and cleans  
gum line

Ergonomic finger tab

Textured for cleaning  
between teeth

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<b>Side Sleeper</b> A forum for users of the Side Sleeper. Moderator Jessica	2	5	Thu Jun 29, 2006 6:39 pm Zendl →
<b>Support</b>			
<b>Questions</b> A forum for customers with questions for Splintek. Moderator Jessica	48	112	Wed Sep 27, 2006 7:41 am RachelM →

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 We have **243** registered users

The newest registered user is **skpsandhoff**

In total there is **1** user online :: 0 Registered, 0 Hidden and 1 Guest [ Administrator ] [ Moderator ]  
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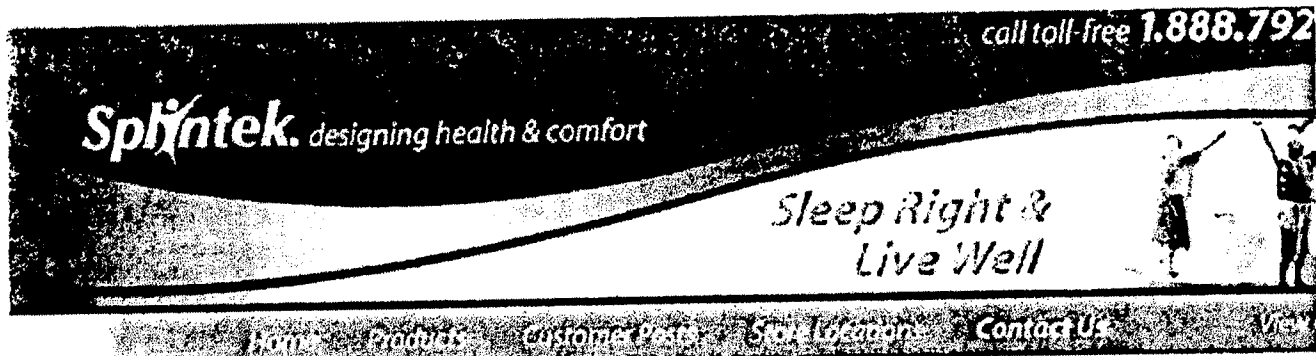
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### Contact Us

Feel free to contact our knowledgeable service representatives by phone, fax, or email.

Toll-Free 1.888.792.0865  
Local (816) 531-1900  
Fax (816) 531-1968

General Information: [sales@splintek.com](mailto:sales@splintek.com)  
Customer Support: [support@splintek.com](mailto:support@splintek.com)

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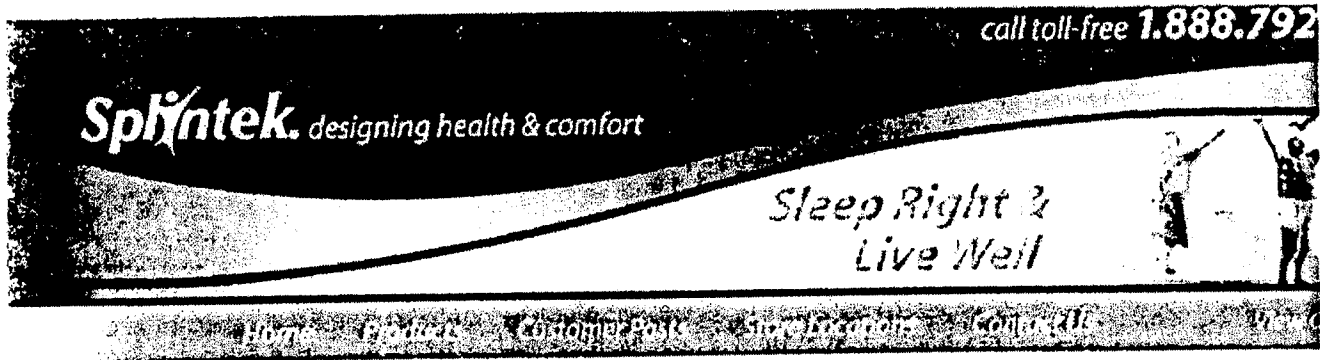
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Night Guard Protects From Teeth Grinding And Clenching

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Please call to place your order.

**Refer-A-Friend** You can receive 10% discount on your next order by referring a friend to us. Just call and tell us the name of your friend you referred and the promotional code: **RAFF10** (cannot be combined with any other discount)

**SleepRight System!** Receive a large discount on the SleepRight Side Sleeping Pillow when purchased with a SleepRight Adjustable Night Guard. Must call to receive discount.

Welcome to Splintek, the company dedicated to designing health and comfort products to help you sleep right and live well. Our SleepRight Adjustable Night Guard protects teeth and dental work from teeth grinding and clenching. Help to ease head, neck, and back tension with our SleepRight Side Sleeping Pillow, made from memory foam.

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